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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HIDEAKI IWASAKI, HIROAKI KAMBAYASHI,
MITSURU NOMURA, NAHO SUZUKI, and KUMIKO KITAMURA

Appeal 2015-001608
Application 13/324,359¹
Technology Center 1600

Before RICHARD M. LEBOVITZ, JEFFREY N. FREDMAN, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims directed to methods of improving the metabolism of a sugar comprising administering panaxadiol or panaxatriol. The Examiner rejected the claims under 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 134. The Examiner's decision is reversed.

¹ The Appeal Brief lists Lion Corporation as the real party in interest. Appeal Br. 1.

STATEMENT OF THE CASE

Appellants appeal from the Examiner's final rejection of pending claims 1–7. Claims 1–7 stand rejected by the Examiner under 35 U.S.C. § 102(b) (pre-AIA) as anticipated by (1) Jung,² (2) Hu,³ and (3) Peng⁴. Ans. 2.

Independent claim 1 is representative. The claim is reproduced below, but with the structural formula omitted. The formula can be found on pages 1–2 of the Claim Appendix of the Appeal Brief.

1. A method for improving the metabolism of sugar in a subject, said method comprising administering to said subject a sugar metabolism-improving agent, wherein the sugar metabolism-improving agent comprises: at least one of a compound having a structure expressed by the following Structural Formula (1) and a compound having a structure expressed by the following Structural Formula (2).

Claim 1 is directed to a method for improving the metabolism of sugar in a subject. The method comprises administering a *compound* of Structural Formula (1) or Structural Formula (2). Independent claim 7 differs from claim 1 only in administering a *composition* comprising a compound of Structural Formula (1) or Structural Formula (2).

² Jung et al., *The protective effect of Ginseng Saponin against high glucose-induced insulin-like growth factor (IGF)-I in primary cultured rabbit proximal tubule cells*, BIO-THERAPY HUMAN RESOURCES CENTER, ANIMAL MEDICAL INSTITUTE DEPARTMENT OF VETERINARY PHYSIOLOGY 1–18 (2009).

³ Hu et al., *Effects of Panaxadiol Saponins on blood glucose and lipid metabolism in experimental hyperglycemia of type 2 diabetes mellitus rats*, Vol. 32, No. 6 J. JILIN UNIVERSITY 1004–1008 (2006).

⁴ Peng et al., *Antihyperglycemic effects of ginseng and possible mechanisms*, 33(6) DRUGS OF THE FUTURE 507–514 (2008).

Structural Formula (1) is panaxatriol (hereinafter, “PT”). Spec. 9: 5–7. Structural Formula (2) is panaxadiol (hereinafter, “PD”). *Id.* at 9: 7–9. The Specification teaches that PT and PD are each an aglycon formed by the removal of a sugar moiety from a plant saponin, a glycoside, and closure of the side chains to form a ring. *Id.* at 9: 10–12. The Specification teaches that PT and PD can be obtained by extraction from ginseng followed by acid hydrolysis. *Id.* at 10:1–18 and 33: 12–18.

REJECTIONS

The Examiner found that the Chemical Abstract Services (“CAS”) indexing disclosed that “the compounds of Hu include the structural formula which is exactly the same as the Structural Formula (2) [PD].” Office Action of Aug. 23, 2013, pp. 3–5. The Examiner further stated that “the chemical structure of PD in Hu was researched by the Chemical Abstract Service and determined to indeed be PD as claimed in claim 1 with a structural formula of formula (2).” Ans. 5.

With respect to Jung, the Examiner found that “the panaxadiol and panaxatriol are presumed to be of the same structure in view of the CAS indexing where the structural formula are exactly the same.” Office Action of Aug. 23, 2013, p. 2. The Examiner also found that “Jung states that ginseng (total ginsenosides) is largely divided into panaxadiol (PD) and panaxatriol (PT) by its chemical structure” which would be understood to mean the compounds obtained from ginsenosides where the sugar moiety is absent. Ans. 4–5.

For Peng, the Examiner stated that the publication “teaches the anti-hyperglycemic effects of ginseng, a plant known to comprise both

panaxadiol and panaxatriol and the use of compositions comprising panaxadiol and panaxatriol for improving sugar metabolism is thus inherently disclosed in Peng.” Final Rejection of Mar. 17, 2014, p. 3.

DISCUSSION

Appellants acknowledge that each of three publications utilized the terminology PT and PD in characterizing the compounds studied in their experiments, but contend that the publication authors made mistakes in the nomenclature. Appeal Br. 6. As evidence, Appellants provided a declaration by Mitsuru Nomura, a co-inventor of the application, having a doctoral degree and experience in the field of metabolism. Nomura Decl. ¶ 4.

Jung publication

Jung states ginsenosides are “largely divided into panaxadiol (PD) and panaxatriol (PT) by its chemical structure.” Jung 2. Jung states that the total ginsenosides PT and PD were purchased from “Korea Ginseng and Tobacco [sic] Research Institute” and tested for activity. *Id.* at 3. Appellants contend that Jung erroneously used the nomenclature PT and PD.

In support of this argument, Dr. Nomura stated that Jung states that ginseng’s total ginsenosides are divided into PD and PT by chemical structure, but that actually Jung is “describing ‘protopanaxadiol(PPD)-type ginsenosides’ and ‘protopanaxatriol(PPT)-type ginsenosides,’ which are the two main classifications of ginsenosides.” Nomura Decl. ¶ 8. Dr. Nomura provides Figure 1 (from the Liu publication) showing that the PPD and PPT ginsenosides contain an open ring which is absent in PD and PT. *Id.* at ¶ 9. Dr. Nomura testifies that Jung states that certain “PT derivatives” (“Re”)

were characterized in the scientific literature; Dr. Nomura provided evidence that the Re compound cited by Jung contained a sugar and open ring, as shown in Figure 1, and thus it is not a PT derivative, which lacks a ring. *Id.* Dr. Nomura states that it is clear from the structures shown in Figure 1 that Re is not a PT derivative and that, accordingly, Jung incorrectly referred to “PT” when intending “PPT.” *Id.* Dr. Nomura made the same argument for an Rg₃ derivative described by Jung as a PD derivative. *Id.* However, Dr. Nomura did show the structure of Rg₃ as he did for Re.

To further support this argument, Appellants cited the Shangguan and Liu publications which Appellants state report that ginsenosides are divided into, *inter alia*, PPD and PPT groups. Appeal Br. 14. Appellants provided evidence from these publications that PPD and PPT differ from PD and PT in having an open ring structure, not a closed ring structure as found in PD and PT. *Id.* at 9. Appellants also cited the Cui, Fujita, and Nagai publications to show that PD and PT are obtained after acid hydrolysis of PPD and PPT, respectively. *Id.* at 9–12.

Upon review, we are persuaded that Jung’s statement that characterizes the fractions used in their experiments as PT and PD is inconsistent with information in other publications. The Examiner did not persuade us that there was a deficit in Appellants’ evidence. Thus, this fact-based evidence from Dr. Nomura’s testimony and scientific publications raises doubts about the identity of the compounds tested in Jung. In response to Appellants’ evidence, the Examiner relied solely on the nomenclature used in Jung, but because Appellants have provided evidence that this nomenclature is erroneous, or at least doubtful, we cannot sustain

the rejection. A preponderance of the evidence does not support the determination that Jung necessarily discloses the claimed compounds.

The rejection of claims 1–7 as anticipated by Jung is reversed.

Hu publication

Hu states that “Panaxadiol Saponins (PDS)” were provided by “Naturally Medical Chemistry Lab of Chemical Department of Jing University.” Hu 1. The Examiner relied on CAS indexing which shows that a structure that corresponds to PD is one of the compounds tested by Hu.

Ans. 3.

Dr. Nomura states the Hu made a mistake in nomenclature. Nomura Decl. ¶ 11. Dr. Nomura states:

“[p]anaxadiol Saponins (PDS) are Ginsenoside substances separated from *Panax ginseng* C.A. Mey., including mainly Rb₁, Rb₂, Re, Rd and Rh₂.” *Hu, Page 1, First Paragraph*. Rb₁, Rb₂, and Re are shown in Figure 1 of Liu above and it is clear that they are not the presently claimed compounds. One of ordinary skill in the art would immediately appreciate that Hu is referring to PPD-type ginsenosides, which are distinct from the presently claimed Formula (1) and (2). The presently claimed compounds are not “panaxadiol saponins.”

Id.

Appellants, citing the Liu publication, provide evidence that “saponins” specifically referred to in Hu, contain a sugar and lack the closed ring at C-20, present in the claimed Formula 1 and 2 compounds. Appeal Br. 18. Dr. Nomura acknowledges that CAS indexed the claimed PD structure for Hu. Nomura ¶ 13. However, in view of the absence of any chemical structure in Hu, and Hu’s specific reference to compounds that are not Formula 1 or 2, but which contain an open ring absent in Formula 1 and

2, Dr. Nomura believes the CAS is an error based solely on the presence of the term “panaxadiol” in the publication. *Id.*

Dr. Nomura’s testimony is supported by a preponderance of the evidence before us. The Examiner did not identify a factual error in it, but relied on CAS indexing. The Examiner did not provide evidence that CAS “researched” the compound, rather than merely identifying the term “panaxadiol” in Hu and associating it with its known structure. Nomura ¶ 13.

Other than CAS, the Examiner did not provide evidence that the “Panaxadiol Saponins (PDS)” of Hu comprise PT or PD. Citing the Cui publication, the Examiner stated that certain products are “formed” from RB₁, but the Examiner did not establish that any of these products are present in Hu’s test composition. Ans. 4. It appears the products cited by the Examiner are produced after chemical treatment (Cui 416 (left-hand col., third paragraph) which was not demonstrated by the Examiner to have been carried out on Hu’s test composition. Consequently, the anticipation rejection by Hu cannot be sustained because the Examiner did not establish by a preponderance of the evidence that Hu described the PD compound as claimed.

The rejection of claims 1–7 as anticipated by Hu is reversed.

Peng publication

Peng describes the anti-hyperglycemic effects of ginseng. Peng (Abstract). Although Peng does not describe PD or PT, the Examiner found such compounds are present in ginseng and thus found that Peng inherently

used them to improve sugar metabolism as recited in claims 1 and 7. Final Rej. 3.

Peng, like Jung, makes the statement that there are two major group of chemical structures, panaxadiols and panaxatriols present in ginseng extracts. Peng 508 (left-hand col., third paragraph). However, as in Hu, in characterizing the content of ginseng extracts, Peng describes compounds which have the open ring structure which is absent from PD and PT. *Id.* (right-hand col., first paragraph); 511 (right-hand col., fourth paragraph). Nomura Decl. ¶ 15; Appeal Br. 12–13. Appellants also cite the Liu and Shangguan publications which identifies PPD and PPT as two of the major constituents of ginseng, each which have the open ring structure and not the closed ring structure of PD and PT. Appeal Br. 18. The Examiner has not provided adequate evidence or reason to doubt the factual evidence cited by Appellants that Peng does not necessarily describe PD and PT as required by independent claims 1 and 7. Consequently, the anticipation rejection by Peng cannot be sustained because the Examiner did not establish by a preponderance of the evidence that Peng described and tested for the activity of PD and PT as claimed.

The rejection of claims 1–7 as anticipated by Peng is reversed.

SUMMARY

The anticipation rejections of claims 1–7 by each of Jung, Hu, and Peng are reversed.

REVERSED